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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/626,038

Applicant(s)

RINMAN, ASE

Examiner

Nikita R Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 29-32, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 23, 6, 7, 10, 12-18, 20-28, 33-35 and 38 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 8, 9, 11 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 and 10 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                                 |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/24/2003</u> . | 6) <input type="checkbox"/> Other: ____.                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 29-32, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of Group II and nonelected species a) and b), there being no allowable generic or linking claim. Examiner states, that claims 36 and 37 depend from claims 30 and 35, which are drawn to a nonelected invention of Group II. Election was made **without** traverse in the reply filed on 01/19/2005.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 07/24/2003 was considered by the examiner.

### ***Claim Objections***

3. **Claims 12, 14-17, 20 and 38** are objected to because of the following informalities: With regard to claims 12 and 14-17 the phrase "the helix shaped wire" in line 2 through all of said claims should read "a helix shaped wire", since "helix shaped wire" is not in claim 1 from which the claims depend, or claims 12 and 14-17 should depend from claim 10 or claim 11. With regard to claim 16 the phrase "add" in line 2 should read "end". With regard to claim 20 the claim should end with a period, not with a coma. With regard to claim 38 the phrase "a

valve assembly” in lines 1-2 should read “the valve assembly”. Appropriate corrections are required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 2, 6, 7, 10, 12, 18, 33, 34 and 38** are rejected under 35

U.S.C. 102(b) as being anticipated by Chaussy et al. (US 6,022,312). Chaussy et al. ('312) teach a valve assembly adapted to be positioned into a urethra in a mammal, including humans, the valve assembly comprising:

**(claim 1)** a) a valve holder (12) comprising a substantially cylindrically shaped body to be inserted into the urethra (Figures 1a and 14), and  
b) a valve housing (13a) comprising a valve (17) controlling an urine flow from a patients bladder, the valve assembly being arranged in a sealed manner between the walls of the urethra (Figure 14), wherein the cylindrical valve holder (12) comprise: a shape memory alloy to provide an expandable element (Figure 14 and column 7, lines 38-41) having the possibility to expand after the insertion of said valve holder (12) to increase its diameter at its upper end to provide a frustoconical portion (Figure 14), whereby the increase of the diameter of the

cylinder at its upper end is more than 15% (Figure 14 – element 12 with the increased diameter at its upper end which is inside the urethra) and whereby the increase of the diameter of said cylindrical valve holder (12) is temperature dependent (column 7, lines 38-47).

**(claim 2)** A valve assembly according to claim 1, wherein the cylindrical valve holder (12) increase its diameter at its lower end (Figure 1a).

**(Claim 6)** A valve holder according to claim 1, wherein the holder (12) and the housing (13a) are detachable from each other when in place in the urethra (column 7, lines 55-67).

**(claim 7)** A valve holder according to claim 1, wherein the holder (12) and the housing (13a) are detachable from each other (column 7, lines 55-67).

**(claim 10)** A valve assembly according to claim 1, wherein the holder (12) is helix shaped wire arranged onto the valve housing (13a) (column 8, lines 33-40).

**(claim 12)** A valve assembly according to claim 1, wherein the increase of the diameter of a helix shaped wire at its upper end is more than 15 % (Figure 5 – element 12' with the increased diameter at its upper end).

**(claim 18)** wherein an increase of the diameter of a cylindrical portion of a valve holder (12) is less than 80% (Figure 4b)

**(claim 33)** A valve according to claim 1, wherein the valve (17) is mechanically controlled (column 7, lines 3-13).

**(claim 34)** A valve according to claim 1, wherein the valve (17) is mechanically controlled independent of the pressure in the bladder to be emptied (column 7, lines 8-13).

**(claim 38)** a method for emptying a patient's urine bladder, whereby the valve assembly in accordance with claim 1 is inserted in the urethra and influenced at time intervals to open and empty a bladder (column 7, lines 2-14).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 13-17, 20-28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaussy et al. (US 6,022,312). Chaussy et al. ('312) teach a valve assembly adapted to be positioned into a urethra in a mammal, including humans, as described in paragraph 5 above, but they do not teach a valve assembly, (claim 3) wherein a valve holder (12) comprises at least two frustoconically shaped portions.

In the absence of showing any criticality the valve holder with at least two frustoconically shaped portions would be a matter of ordinary engineering design choice, and would have been an obvious modification to one of ordinary skill in

the art of the shape of the valve holder to hold securely the valve holder in place when inserted into the patient's urethra.

Chaussy et al. ('312) teach a valve assembly, wherein the cylindrical valve holder (12) increase its diameter at its upper end more than 15%, or wherein the increase of the diameter of a helix shaped wire at its upper end is more than 15%, and wherein the cylindrical valve holder (12) increase its diameter at its lower part, as described in paragraph 5 above, but they do not teach a valve assembly, (claims 13-17) wherein the increase of the diameter of a cylinder or a helix shaped wire at their upper end is at least 40 %; or wherein an increase of the diameter of a helix shaped wire at its lower end is at least 10% or 20% after expansion.

The increase of the diameter of the cylinder and the helix shaped wire at their upper end of at least 40%, or the increase of the diameter of the helix shaped wire at its lower end of at least 10% to 20% is generally an obvious matter of design choice to practitioner in the medical art, and would have been an obvious modification to one of ordinary skill in the art of the diameter and the helix shaped wire to hold securely the valve assembly in place when inserted into the patient's urethra. The selection of a particular size of any valve assembly having the cylinder and the helix shaped wire is of no patentable significance. Chaussy et al. ('312) teach a valve assembly, as described in paragraph 5 above, but they do not teach a valve assembly, (claim 20) wherein a total length of the assembly is less than the length of the female urethra; or (claim 22) is

between 5 and 40 mm, preferably 5-30 mm; or (claim 21) wherein the total length of a valve is less than 60 mm.

The length of the valve assembly or the valve is generally an obvious design choice to practitioners in the medical art. The selection of a particular length of any valve assembly or valve is of no patentable significance. It would have been an obvious modification to one of ordinary skill in the art of the length of the valve assembly to provide precise fit of said valve assembly inside the urethra according the length of the urethra where it is intended to be inserted. Chaussy et al. ('312) teach a valve assembly, as described in paragraph 5 above, and wherein the valve assembly has a bending flexibility (column 8, lines 14-16), but they do not teach a valve assembly (claims 23-28) wherein at least a part of the length of a valve assembly has a bending stiffness higher than 0.0004 Nm<sup>2</sup> (Newton square meter).

It would have been obvious to one of ordinary skill in the art at the time of the invention to determine through routine experimentation an appropriate bending stiffness and length for implementing the valve assembly, including valve assembly within the range of bending stiffness and length Applicant provides in the claims.

Chaussy et al. ('312) teach a valve assembly, as described in paragraph 5 above, and wherein the valve may be opened by means of a opening force (column 7, lines 8-14), but they do not teach a valve assembly, (claim 35)



wherein a valve may be open by means of a opening force being between 10 to 200 mN.

It would have been obvious to one of ordinary skill in the art at the time of the invention to determine through routine experimentation an appropriate force for opening the valve within the range of force Applicant provides in the claim.

***Allowable Subject Matter***

8. **Claims 4, 5, 8, 9, 11 and 19** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art, either alone or in combination, teaches or suggests a valve assembly adapted to be positioned into a urethra in a mammal, including humans, as claimed, wherein either

**(claim 4)** a valve holder comprises at least two frustoconically shaped portions at one end of a cylinder; or

**(claim 5)** wherein a valve holder comprises at least two frustoconically shaped portions at one end of a cylinder as well as at least one frustoconically shaped portion at the opposite end thereof; or

**(claim 8)** wherein a valve holder includes a first portion exhibiting a frustoconical shape, a second portion being essentially cylindrical and a third portion exhibiting

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a frustoconical shape directed in opposite direction in relation to the first portion;

or

(**claim 9**) wherein the valve holder includes a first portion exhibiting a

frustoconical shape, a second portion being essentially cylindrical and a third portion exhibiting a frustoconical shape directed in opposite direction in relation to the first portion; or

(**claim 11**) wherein a holder comprises a helix shaped wire threaded on external treads arranged on the outside of a valve housing; or

(**claim 19**) wherein a valve holder comprise an expandable element having the possibility to shrink upon removal of a valve housing; or

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kulisz et al. ('646) ; Redmond et al. ('236) ; Ardito ('999) ; Von Idrestein et al. ('580) ; Migachyov ('413) ; Kulisz et al. ('623) ; Isaacson ('842) and Sachdeva et al. ('258).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



February 28, 2005.

Nikita R Veniaminov  
Examiner  
Art Unit 3736



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